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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,737	01/29/2004	Roney Graf	33901/US	5736
7590 FISH & RICHARDSON P.C. 1717 MAIN STREET SUITE 5000 DALLAS, TX 75201			EXAMINER PATEL, PRITESH ASHOK	
			ART UNIT 4158	PAPER NUMBER
			MAIL DATE 09/04/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,737

Applicant(s)

GRAF ET AL.

Examiner

PRITESH PATEL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/29/2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) 1-38 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-85/86)
Paper No(s)/Mail Date 1/29/04 and 12/19/06
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Inventor's Patent Application
6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 1/29/2004 and 12/19/2006 were filed before the mailing date of the First Office Action on the Merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

2. Receipt is acknowledged of papers, German Application No. 201 12 507.3 and German Application No. 101 63 329.7, submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The PCT application, international application No. PCT/CH02/00412, has not been submitted.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show a cannula and how the cannula can be fitted onto the front part of the front casing as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 10 is objected to because of the following informalities: The first part of claim 10 reads "The administering apparatus as set forth in claim 10," this is incorrect because a claim cannot refer to itself. Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-38 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8, 16, 24, 26, and 27 of copending Application No. 10/767976. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim similar subject matter concerning the same embodiment of the invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 6-8 and 16 are all dependent on independent claim 1 in the copending application. Claims 26 and 27 are dependent on claim 25 (Claim 25 is dependent on Claim 1) in the copending application. Claim 1 of the copending application discloses front and rear casing sections for detachable connection, a piston, a piston rod, a drive element, and first latching element. In Claim 6 the latching engagement for the latching element is described as fixing the front casing to the rear casing with and counter to the advancing direction. The advancing direction is the same as the longitudinal axis of the tube like structure and is the same as axial guide as described in the application being examined. Claim 16 in the copending application discloses the dosage setting member completing the limitations that are attributed to Claim 1 in the application under

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examination. Claims 24, 26, and 27 disclose details about the size and gauge of a cannula which meets the limitations in Claims 22 and 23 of the application under examination completely.

The application has many claims that are concerned with the axial guides and how they are shaped; the engagements with which they are coupled are not discussed because they must be in pairs to function. The shape of these axial guides does not change their function and therefore does not provide enough of a difference to refute double patenting.

The contents of the Claim 1 of the application are reworded and put into the other independent claims of the same application, but their limitations are reached with the same corresponding claims in the copending application as described above.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 1-21 and 24-38 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Harris (U.S. Patent No. 5226895) in view of Buch-Rasmussen et al. (U.S. Patent No. 6582408 B1).
8. Concerning claims 1, 18, 24, 35, 36, and 37, Harris discloses in figures 1 and 2, an injection apparatus comprising a reservoir module having a front casing section (12) which comprises a disposable reservoir (14) a blocking means (71); a first connecting means, (19), comprising a first latching element; a piston (36); a piston rod (56) which comprises a returning blocking means (66), located on the surface of the piston rod (64), comprising a row of serrated teeth which prevent the piston rod from rotating relative to the front casing section; a dosing and activating module comprising a rear casing (86 and 100) which comprises a second connecting means (94), comprising a second latching element; a dosing and drive device (72); and a dosage setting member (104) which is moved by the dosing and drive device and which engages with the piston rod; wherein the connecting means form an axial linear guide. Harris fails to disclose an axial guide on a casing of the apparatus. Buch-Rasmussen et al. discloses means for coupling the dosing assembly and the cartridge assembly, respectively rear and front casings, as being a series of mechanisms including bayonet locks, long protruding elements that can axially align two casings (Column 3, Lines 8-14). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Harris by incorporating multiple axial alignments in the form of

multiple bayonet locks as taught by Buch-Rasmussen et al.

Concerning claims 2, 3, 4, 5, 6, 7, and 8, Harris fails to disclose axial guides and variations of the sort. Buch-Rasmussen et al., as disclosed above limitation, he discloses the use of bayonet locks to connect the front and rear casings. The disclosure also allows for multiple locks and all variations of bayonet locks (Column 3, Lines 8-14). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Harris by using bayonet locks as taught in Buch-Rasmussen et al. as axially aligned elements. It would have been further obvious to one of ordinary skill in the art at the time of the invention that there are many variations of a bayonet lock and that counterparts of the axial guides will be on an opposite casing section to the casing section containing the axial guides.

9. Concerning claims 9,10,11,12,13, 14, 15, 16, 17, 19, 20, 21, 25,26, 27, 28, and 29, and in addition to the above disclosure, Harris discloses in Figures 4 and 5 the dosage setting member (104) engaging with the rear casing section (86 and 100) in pre-set rotational angular positions so as to be linearly and axially guided, wherein a locking projection (106) and a locking recess (104) are in locking engagement and can be moved by a restoring elasticity force. Harris discloses in Figure 7 the dosing and drive device (72) and the piston rod (56) engaging with each other. Harris discloses in Figures 5 and 9 the dosing movement being a rotational movement about a threaded longitudinal axis of the piston rod. Harris does not disclose an axial guide that aligns the two casing sections. Buch-Rasmussen et al. discloses an axial guide as described in the above disclosure (Column 3, Lines 8-14).

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Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Harris with bayonet locks on the casing sections as taught by Buch-Rasmussen et al.

Concerning claims 30, 31, 32, 33, and 34 Harris discloses in figures 5-9 the dosage setting member (104) comprises a stopper (distal part of 104) and the front casing section (12) forming a delivery stopper (118). The dosing and drive device (72) and the dosage setting member (104) engage with each other and wherein the dosage setting member (104) forms a stopper for the dosing and drive device (72). Harris fails to disclose a sleeve-shaped reservoir part and a piston that couple with each other and a sleeve-shaped mechanism holder that houses the reservoir/piston coupling. Buch-Rasmussen et al. discloses a housing capable of containing a removable cartridge that has a movable stopper that moves in an advancing direction (Claim 10).

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Harris with a housing comprising a removable cartridge and with a piston within as taught by Buch-Rasmussen et al.

10. Concerning claim 38, Harris discloses the front and rear casing sections, a piston, a piston rod, a disposable casing section, and a dosage setting mechanism, and other components as listed above (Refer to Figures as indicated above). Harris does not disclose an alignment mechanism or a removable cartridge with a piston. Buchman-Rasmussen et al. discloses bayonet locks, generally axially aligned, and a removable cartridge that contains a piston.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the

invention to modify Harris with bayonet locks and a removable cartridge with a piston as taught by Buchman-Rasmussen et al. The previous disclosure in this action also meets the limitation of Claim 38 of the patent application.

11. Claims 22 and 23 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Harris in view of Buch-Rasmussen et al. in further view of Dibiasi et al. (U.S. Patent 6200296 B1). Harris in view of Buch-Rasmussen et al. discloses an administering apparatus with two casing sections that are in removable attachment with each other and axially align. The front casing has a junction for attachment of a needle or cannula. Harris in view of Buch-Rasmussen et al. does not disclose the use of smaller cannula sizes with the administering apparatus. Dibiasi et al. discloses the use of smaller cannula, such as a 31 gauge or 32 gauge cannulae (Column 2, Lines 4-40). The smaller gauge size would benefit Harris in view of Buch-Rasmussen by providing less pain for the patient and so improving the usability of the invention. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Harris in view of Buch-Rasmussen with a cannula of smaller size, specifically 31 gauge or 32 gauge, as taught by Dibiasi et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRITESH PATEL whose telephone number is (571)270-

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7025. The examiner can normally be reached on Monday-Friday 7:30Am-5:00PM, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. P./

8/13/2008

Examiner, Art Unit 4158

/Gary Jackson/

Supervisory Patent Examiner

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